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ORIGINAL SUBMISSION

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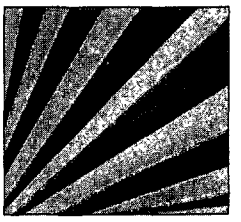

CONSOLIDATED
GROWERS & PROCESSORS

1999 NOV 17 P 2:29

November 16, 1999

Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.,
Washington, DC 20204

RE: Notice of a GRAS Exemption Claim – Hempseed Oil

Dear Madam/Sir:

Consolidated Growers and Processors, Inc. (CGP) is pleased to submit our Notification of GRAS Determination for the substance commonly known as hempseed oil. Consolidated Growers and Processors, Inc. (CGP) is making notification pursuant to 21CFR§170.36 that hempseed oil, in its intended use, is Generally Recognized as Safe (GRAS) and as such is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (the act). CGP is making this notification based upon historical experience of hempseed oil's common use in food prior to January 1, 1958.

The Notification of a GRAS Exemption Claim is attached in triplicate for your review. The data and information that are the basis for the GRAS determination will be sent to FDA upon request.

If you have any questions, please feel free to contact me directly at (917) 748-6071 or via e-mail at dushenkov@aol.com.

Thank you for your kind consideration.

Sincerely,

Slavik Dushenkov, Ph.D.
Executive Vice President
Consolidated Growers and Processors, Inc.

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P.O. BOX 2228 MONTEREY, CALIFORNIA 93942-2228 USA
PHONE 888-333-8CGP • FAX 888-999-8CGP • e-mail: info@congrowpro.com
INTERNATIONAL CALLS / VOICE MAIL 310-285-3339

Notice of a

GRAS Exemption Claim

for

Hempseed Oil

Submitted By:

November 16, 1999 _____

Slavik Dushenkov, Ph.D.
Executive Vice President
Consolidated Growers & Processors, Inc.
P.O. Box 2228
Monterey
California 93942-2228

Submitted to:
Office of Premarket Approval (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.,
Washington, DC 20204

GRAS Exemption Claim for Hempseed Oil

1. GRAS Exemption Claim

a. Notifier name and address

Slavik Dushenkov, Ph.D.
Executive Vice President
Consolidated Growers & Processors, Inc.
CGP, Inc.
P.O. Box 2228
Monterey, California 93942-2228

b. Name of Notified Substance – common or usual name

Hempseed oil (also known as – hemp seed oil, hemp oil and hempoil)

c. Conditions of Use

(1) Food in which substance is to be used

The use of hempseed oil is comparable to other shelved and commodity oils such as soybean, rapeseed, cottonseed, olive, corn and peanut oil sold in today's supermarket, however, it's nutritional values far surpass those of conventional oil. Oils from hemp seeds contain valuable cis-polyunsaturated fatty acids which positively affect the metabolism of numerous human and animal metabolic pathways and the function of cell membranes. These fatty acids are essential and may not be substituted by each other or by their trans counterparts.

Hempseed oil is an alternative wherever such oils, butter or butter-like products are used. It can also be used as a high quality salad oil in dressings, marinades and sauces. Mechanically cold-pressed (not solvent extracted), unrefined oils have the characteristic aroma and flavor of the seed from which they were pressed.

Hempseed oil will find utility as a functional ingredient in finished products such as, baked goods, breads, pastries, pasta, snacks, cooking oils, non-dairy creamers, cheese, confections, spreads, dips, salad dressings, beverages, margarines, shortenings, etc.

Adding food made with hempseed oil to the diet seems to lower risks of heart attacks because omega-3 fatty acids reduce the clotting tendency of the blood and improve

cholesterol profiles. They also have a natural anti-inflammatory effect that makes them useful for people with arthritis and autoimmune disorders.

(2) **Levels of use in such foods**

Hempseed oil, as with other vegetable oils (triglycerides) are used extensively as a food and in food formulations. The use level of hempseed oil, as a food additive, is limited to the minimum amount required to produce the intended effect.

(3) **Purposes for which the substance is used**

Hempseed oil may be used as flavoring agent or adjuvant solvent or vehicle or stabilizer or thickener emulsifier or texturizer.

d. **Basis for GRAS determination**

The basis on which Consolidated Growers & Processors, Inc. is seeking GRAS determination is historical experience based on common use in food prior to January 1, 1958.

2. Identity and Specifications

a. **Chemical name**

Hempseed oil

b. **Chemical Abstracts Service (CAS) registry**

8016-24-8

c. **Enzyme Commission (EC) number**

Not Applicable

d. **Empirical formula**

$(R^1COO)CH_2 \bullet CH(OOCR^2) \bullet CH_2(OOCR^3)$; where $R^{(1,2\ \&\ 3)} = CH_3(CH_2)_N$ where N = 7 – 23

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e. **Structural formula**

Hempseed oil, as are all vegetable fats and oils, is an ester of fatty acids and glycerol. R^1, R^2 and R^3 (below) may be of the same fatty acid residue, but in general the fats are mixed triglycerides, with each fatty acid being different.

$H_2C\text{-}OOCR^1$
|
$HC\text{-}OOCR^2$
|
$H_2C\text{-}OOCR^3$

Where: $R^{(1,2\ \&\ 3)} = CH_3(CH_2)_N$ where $N = 7 - 23$

f. **Quantitative composition**

Hempseed oil is the cold-pressed edible oil derived from the seed of certain varieties of the *Cannabis sativa* plant of the family Cannabinaceae. The crop is commonly known as industrial hemp. Chemically, hempseed oil is a mixture of triglycerides, composed of both saturated and unsaturated fatty acids. Hempseed oil is rich in the essential fatty acids linoleic and linolenic acids, representing approximately 80% of its fatty acid composition. The typical fatty acid composition of hempseed oil is:

Hempseed oil Fatty Acid Profile (major acids):

C16:0 Palmitic	5 – 12 %
C16:1 Palmitoleic	0 - 0.5 %
C18:0 Stearic	1.0 – 4.5 %
C18:1 Oleic	10 – 16 %
C18:2 Linoleic	45 – 65 %
C18:3 Linolenic	14 – 30 %
C18:3 Gamma Isomer (GLA)	1.0 - 3 %
C20:0 Arachidic	0 - 2 %
C20:1 Eicosenoic	0 - 1 %
C22:0 Behenic	0 - 1 %

For additional information related to the quantitative composition hempseed oils, please refer to Attachment III – Composition, Properties and Health Benefits of Hemp (*Cannabis sativa* L.) Seed Oil – Phytomedics, Inc., 1999 (Leizer, Ribnicky et al. in press).

g. **Method of manufacture**

Hempseed oil is produced by cold-pressing the hulled or de-hulled oil-bearing seed of the Industrial Hemp (*Cannabis sativa* L.) plant. The resultant oil can be further processed by means of refining, bleaching and deodorizing. These unit processes can be employed to improve the flavor, odor and color of the hempseed oil without altering the basic chemical structure of the oil. During crushing and subsequent processes, either an inert gas or vacuum environment is maintained around the oil to preserve its oxidative stability. Often an antioxidant is added to the oil to extend its usable shelf-life and prevent oxidation during storage. The antioxidant most often used is vitamin E.

Packaging of hempseed oil should occur quickly after pressing in order to avoid the detrimental effects of oxidation on its stability and therefore shelf-life. Whenever possible bottled oil should be filled and capped in an inert gas environment such as nitrogen. The bottled oil should be protected from direct sunlight and heat. Typically, hempseed oil is packaged in an opaque bottle to protect it from direct exposure to sunlight. It is suggested that hempseed oil be stored in the refrigerator once the bottle has been opened to preserve its freshness and maximize its usefulness. If hempseed oil is stored in bulk storage containers (tanks, totes, drums) it should be held under an oxygen free (nitrogen purged, e.g.) environment whenever feasible.

h. **Characteristic properties**

Hemp seeds contain 20 - 25% high quality protein and up to 40% fat in the form of excellent quality oil. Hempseed oil has a remarkable fatty acid profile, being high in the desirable omega-3s and also delivering some GLA (gamma-linolenic acid) that is absent from the fats in common diets. Nutritionally oriented doctors believe all of these compounds to be beneficial to health.

Hempseed oil contains approximately 57% linoleic (LA) and 19% linolenic (LNA) acids, in the three-to-one ratio that matches human optimal nutritional needs. These are the essential fatty acids (EFAs)-which the body cannot make and which must be obtained from dietary sources. The best sources are oils from freshly ground grains and whole seeds, but EFAs are fragile and quickly lost during processing. EFAs are the building blocks of longer chain fats, such as eicosapentaenoic (EPA) and docosahexaenoic acid

(DHA) that occur naturally in the fat of cold-water fish like sardines, mackerel, salmon, bluefish, herring, and, to a lesser extent, tuna.

Udo Erasmus is an expert in the field and author of Fats that Heal, Fats that Kill (Erasmus 1996). He states that, "Hempseed oil contains more EFAs than flax and actually tastes good. It is nutty and free from the objectionable undertones of flax oil. I use it on salads, baked potatoes, and other foods..."

"Like flax oil, hempseed oil should be stored in the refrigerator, used quickly, and never heated. Unlike flax oil, hempseed oil also provides 1.7% gamma-linolenic acid (GLA). There is controversy about the value of adding this fatty acid to the diet, but many people take supplements of it in the form of capsules of evening primrose oil, black currant oil, and borage oil. My experience is that it stimulates growth of hair and nails, improves the health of the skin, and can reduce inflammation. I like the idea of having one good oil that supplies both omega-3s and GLA, without the need to take more capsules."

Hemp (*Cannabis sativa* L.) seed oil is valued primarily for its nutritional properties as well as for the health benefits associated with it. Although its fatty acid composition is most often noted, with oil content ranging from 25 – 35%, whole hemp seed is additionally comprised of 20 – 25% protein, 20 – 30% carbohydrates, and 10 – 15% fiber, along with an array of trace minerals (Deferne and Pate 1996; Erasmus 1999).

Hempseed oil is comprised almost entirely of fatty acids, with an essential fatty acid content of 75%, especially linoleic (LA) and linolenic (LNA) acids in a 3:1 ratio.

Hempseed oil contains linoleic (LA) and α-linolenic acid (LNA) as its major omega-6 and omega-3 fatty acids, respectively. These fatty acids comprise the most desirable contents of the oil, especially due to the ratios in which they exist. The 3:1 ratio of LA to LNA is alleged to be optimal for nutrition (Calloway and Laakkonen 1996; Deferne and Pate 1996). The additional presence of gamma-linolenic acid (GLA) in hempseed oil ultimately makes its nutritional value superior to most comparable seed oils. The myriad of benefits reported to be attributable to omega-3 fatty acids include anti-cancer, anti-inflammatory, and anti-thrombotic properties. In addition, dietary omega-3 fatty acids help to increase general metabolic rates and promote the burning of fat (Erasmus 1999).

The reported health benefits of hempseed oil, and especially the essential fatty acids, are well documented. When diets are supplemented with omega-6 and omega-3 fatty acids in the proper 3:1 ratio, numerous benefits to health are achieved, including but not limited to greater resistance to cancer, inflammation, and blood clotting. A general increase in metabolism and lower overall blood cholesterol levels have also been observed.

In addition to all these positive health benefits associated with hempseed oil, there appears to be a complete lack of negative effects from its consumption. To date, there

have been no reported cases of toxicity from the ingestion of hemp seed oil (Leizer, Ribnicky et al. in press).

i. **Potential human toxicants**

CGP is currently unaware of any human toxicants.

j. **Specifications for food grade material**

See Attachment I & II

3. Self-limiting Levels of Use

None known by CGP at this time.

4. Scientific Procedures GRAS Determination

Not Applicable

5. Common Use GRAS Determination

Throughout history and in separate parts of the world, hemp seeds and hempseed oil have been used as a vital source of food and nourishment. The domestication of *Cannabis* may well have occurred 6500 years ago (Vavilov 1992) in Asia (Fleming and Clarke 1998). The history of the use of hemp seed as a food can be documented as far back as 2700 BC (Dewey 1913) in ancient Chinese writings. These writings reflect that cannabis was used by the Chinese for a variety of uses including fiber, oil and as a medicine. Clark and Gu (Clarke and Gu 1998) recently reported that Hmong people of the China/Vietnam border region preserved the ancient tradition of hem use. The Chinese Book of Songs has the following mention of the use of hemp seed for food,

"Farmers eat hemp seeds in September"

Hemp was commonly grown as a seed crop throughout the Spring and Autumn period (770 to 476 BC), Warring States period (476 to 221 BC), the Qin dynasty (221 to 207 BC), and the Han dynasty (206 BC to 220 AD). The Li Qi places hemp among the "five grains" of ancient China, which also included barley, rice, wheat and soybeans. Hemp seed remained a staple of the Chinese diet through the 10th century (Li 1974).

Hemp was probably the earliest plant cultivated for the production of a textile fiber. The "Lu Shi," a Chinese work of the Sung dynasty, about 500 A.D., contains a statement that the Emperor Shen Nung, in the twenty-eighth century B.C., first taught the people of China to

cultivate "ma" (hemp) for making hempen cloth. The name ma occurring in the earliest Chinese writings designated a plant of two forms, male and female, used primarily for fiber. Later the seeds of this plant were used for food (Bretschneider 1893). The definite statement regarding the staminate and pistillate forms eliminates other fiber plants included in later times under the Chinese name ma. The Chinese have cultivated the plant for the production of fiber and for the seeds, which were used for food and later for oil.

Hemp was first introduced into Europe around 500 – 1000 AD. It is known that hemp was in wide cultivation in Europe by the Sixteenth century. It was cultivated for its fiber and seed. The seed was cooked with barley and other grains and eaten (Birrenbach).

The use of hempseed oil as a source of food is mentioned in the1895 Yearbook of the United States Department of Agriculture (Hicks 1986) with the following passage:

'Hempseed oil is used to a considerable extent in the preparation of paints and varnishes, although it does not dry as readily as linseed oil. In Europe it enters largely into the composition of soft soaps. Sometimes it is used in the Old World as an illuminant and, rarely, for food.'

Hemp has been grown in the Ukraine for centuries. Before the 1950's the area under cultivation in Ukraine exceeded 150,000 ha. Hemp fibre was widely used in the manufacture of technical products, and was used by peasants to make cloth, clothes and household goods. Hemp seeds, after different kinds of processing, and hemp seed oil, were used as food and for technical purposes (Goloborod'ko 1995).

Hemp seeds and hemp seed oil were used as a staple in the daily lives of Ukranians. In the book "Customs, Beliefs, Cuisine and Beverages of Malorussians" (Markevich 1860), written in 1860, Nikolai Markevich chronicles the daily life of the Ukrainian people. In it he clearly demonstrates, through the common recipes of the time, how hemp seeds and hempseed oil were used by the mass population of the Ukraine. The following excerpts are included as evidence:

> Page 150
> *2. Borshch*: Cabbage, Beets, and Meat are placed in a pot, they are mixed with good pork fat and are poured over by beet kvass [sour drink]. When borshch boils it is salted and then pork fat with onions are added. It is served with sour cream. During lent - instead of meat, fat and sour cream, fish and hemp oil with fried onions are added.
>
> Page 154
> 27. *Kutia:* Best in January during supper. It may be barley, wheat or rice. Crush barley or wheat and boil in water. It is served with milk: hemp, poppy seed, almond or with thinned honey, which is called - syta. Add almonds, walnut and hazelnut to syta. Mix well. Whipped cream may be added to kutia.

The following excerpts from the book "Hemp"by Plotnikov S.I. P: 290-292 (Plotnikov 1931), clearly demonstrates the extensive usage of hemp seed and hemp seed oil as food sources in the Ukraine in 1931.

> In its raw state (whole seed) hemp seed is a very valuable feed for different types of birds - small songbirds, pigeons, chicken and turkeys. It has been noted that in those regions where hemp production is intensive, chickens are distinguished by higher egg laying and they do not suffer as much from common diseases.
>
> Slightly fried and crushed in a mortar, hemp seed is mixed in with plain rye or wheat dough, which provides very tasty and nutritious bread.
>
> Hemp oil, which is received by extraction, is of straw colour and almost does not have any odour. Ordinary pressed oil is of green-brown colour with a very strong characteristic odour and taste. In recent time several methods of hemp oil bleaching and deodorizing were introduced. Such purified or refined hemp oil, in its colour and taste, is reminiscent of higher varieties of salad oils from other origins - olive oil, mustard oil and other. Successful research has been done on utilizing it in fish-canning and confectionary industries.
>
> Citizens of hemp growing regions are becoming accustomed to hemp oil and they value its palatability and nutritious value higher than sunflower oil. Buckwheat porridge, when extensively poured over by hemp oil, is considered to be the most popular meal amongst all lumberjacks of the western oblasts and other regions where hemp is grown. As a meal, very rich in carbon, it provides a lot of muscular strength, which is necessary for a lumberjack during his hard work.

Hemp seed oil usage in the Ukraine during the 1930's is further demonstrated by Ivanoff N.N. in his 1938 Biochemistry of cultivated plants. (Ivanoff 1938) p.: 206. The following excerpts are cited:

> Hemp oil is used in the fish-canning industry and in the confectionary industry.
>
> **Utilizing the seed.** Hemp seeds are used for oil extraction. As it was mentioned earlier, hemp seed oil is obtained by either extracting it with dissolvents or by pressing. Oil obtained in this manner is subjected to precipitation and further refinement. Refined oil in many cases is used for consumption...

In the United States, hemp was and continues to be recognized as a food by virtue of Executive Order 10480. Source: The provisions of Executive Order 10480 of Aug. 14, 1953, appear at 18 FR 4939, 3 CFR, 1949-1953 Comp., p. 962 (Executive Order 10480 1953)

,unless otherwise noted. Executive Order 10480 – "Further providing for the administration of the defense mobilization program", signed into law by the President of the US on August 14, 1953, the President of the US, it states,

> By virtue of the authority vested in me by the Constitution and laws of the United States, including the Defense Production Act of 1950, as amended (50 U.S.C. App. 2061 et seq.), and as President of the United States and Commander in Chief of the armed forces of the United States, it is hereby ordered as follows:
>
> Part I. General Direction of Program
>
> Section 101
>
> (a) The Director of the Federal Emergency Management Agency shall, on behalf of the President, coordinate all mobilization activities of the executive branch of the Government, including all such activities relating to production, procurement, manpower, stabilization, and transport. Every officer and agency of the Government having functions under the Defense Production Act of 1950, as amended, delegated, redelegated, or otherwise assigned thereto by or under the authority of the President after the date of this order (whether heretofore or hereafter acquired, or acquired by this order) shall perform the said functions subject to the direction and control of the Director of the Federal Emergency Management Agency.
>
> Within Executive Order 10480, Part IV. General Provisions, Section 601 certain terms are defined. Paragraph (h) states, "The term "food" shall mean all commodities and products, simple, mixed, or compound, or complements to such commodities or products, that are capable of being eaten or drunk by either human beings or animals, irrespective of other uses to which such commodities or products may be put, at all stages of processing from the raw commodity to the products thereof in vendible form for human or animal consumption. For the purposes of this order the term "food" shall also include all starches, sugars, vegetable and animal fats and oils, cotton, tobacco, wool, mohair, *hemp*, flax fiber, and naval stores, but shall not include any such material after it loses its identity as an agricultural commodity or agricultural product.

Executive Order 10480 has been amended over the years, with sections added, altered or deleted but the most recent Executive Order No., 12919, National Defense Industrial Resources Preparedness. Executive Order No. 12919, dated June 3, 1994, addresses national defense industrial resource policies and delegates to certain Cabinet members authorities conferred upon the President by the Defense Production Act of 1950, as amended, 50 U.S.C. App. 2061-2170 (the Act).

Section 201 (a) (1) of the Executive Order delegates to the Secretary of Agriculture (the Secretary) this authority of the President with respect to contracts for food resources, food resource facilities, and domestic distribution of farm equipment and commercial fertilizer. At Section 901 (e), the Executive Order defines "food resources" as commodities or products that are capable of being ingested by either human beings or animals and includes hemp, among other crops.

In a letter dated June 19, 1995 from Dan Glickman, Secretary, Department of Agriculture further emphasizes hemps use as a food resource in response to Ms. Debby Moore, President, Kansas Environmentalists for Commerce in Hemp, he states (Letter 1995), "At Section 901 (e), the Executive Order defines "food resources" as commodities or products that are capable of being ingested by either human beings or animals and includes hemp, among other crops."

Further evidence that hempseed oil is considered a food comes in the form of a response by Lyn Goosens, MPH, RD of the Office of Consumer Education, FDA, CFSPAN regarding the safety of hempseed as a salad oil. In the response letter (Letter 1999), it states "Hempseed oil is an eatable oil, it drawback is that it is not stable and can only be kept a week or two and it becomes rancid. It is not a "drug" substance."

Hempseed oil is currently being used in food and as a nutraceutical. Over hundred food products containing hempseed oil are marketed in Canada. The list of these products includes cooking oil, numerous baked goods, granola bars etc. Among others, Fresh Hemp Foods Ltd.(P.O. Box 2311, Winnipeg, Manitoba, Canada, R3C 4A6. http://www.hemperor.com) actively markets products containing hemp oil. In Europe hempseed oil is marketed both as a nutritional supplement and food additive by Finola (Finola, PO Box 236 FIN-70100 KUOPIO, Finland. http://www.finola.com). Hempseed oil is sold in the United States by several companies. Galaxy Global Eatery (15 Irving Place, New York, NY, 10003. http://www.galaxyglobaleatery.com) not only sales hempseed oil but also serves several dishes containing hempseed oil in the restaurant. The Ohio Hempery, (PO BOX 18,Guysville, OH 45735. http://www.hempery.com) successfully markets hempseed oil in the US for variety of purposes: "The nutty flavor of Hemp Seed Oil brings out the best in a salad when used in your favorite dressing. Use Hemp Seed Oil over baked potatoes, rice, pasta or steamed fresh vegetables (instead of butter or margarine) for a flavor to delight the taste buds".

6. Unfavorable information

No unfavorable information regarding the use of hempseed oil as a food or food additive is known by Consolidated Growers & Processors at this time.

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Attachment I

CONSOLIDATED
GROWERS & PROCESSORS

SALES SPECIFICATION

Cold-Pressed Hempseed Oil

Description: *Cold Pressed All Natural hempseed oil is extracted at temperatures less than 50° C from seeds of the Cannanbis Sativa plant, without the use of chemicals, thus preserving the natural antioxidants and tocopherols. Cold pressed hempseed oil is a rich green in color with a delicate nutty flavor. Hempseed oil has a very high content of unsaturated fats and is a rich source of the essential fatty acids, linoleic and alpha-linolenic fatty acids in what is considered the perfect ratio of 3:1.*

Hempseed oil is a perfect alternative to other conventional oils for use in salads, marinades, sautés and dipping sauces. It is also an excellent emollient and can be easily formulated into personal care products such as soaps, shampoos, skin creams and lotions.

Characteristics	Unit	Specifications
Appearance	Compares to standard	Clear, green liquid
Odor	Compares to standard	Virtually none
Refractive Index @ 40° C	N/A	1.4690 – 1.4720
Free Fatty Acid (% as oleic)	%	2.0 maximum
Acid Value	mg KOH/g	4.0 maximum
Iodine Value	g I_2/100 g	145 – 165
Peroxide Value	meq/kg	5 maximum
Moisture	%	2 0 max
Fatty Acid Profile (major acids):		
C16:0 Palmitic	%	5 – 12
C16:1 Palmitoleic	%	0.5 maximum
C18:0 Stearic	%	1.0 – 4.5
C18:1 Oleic	%	10 – 16
C18:2 Linoleic	%	45 – 65
C18:3 Linolenic	%	14 – 30
C18:3 Gamma Isomer (GLA)	%	1.0 minimum
C20:0 Arachidic	%	2 maximum
C20:1 Eicosenoic	%	1 maximum
C22:0 Behenic	%	1 maximum

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Attachment II

CONSOLIDATED
GROWERS & PROCESSORS

SALES SPECIFICATION

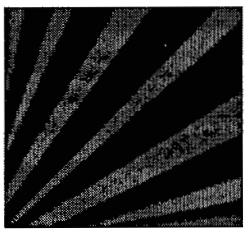
Refined, Winterized & Deodorized Hempseed Oil

Description: *Cold Pressed All Natural hempseed oil is extracted at temperatures less than 50° C from seeds from the Cannanbis Satıva plant, without the use of chemicals, thus preserving the natural antioxidants and tocopherols. The refined oil is winterized, clear, and bright with virtually no flavor or odor. Hempseed oil is a rich source of the essential fatty acids, linoleic and alpha-linolenic fatty acids in what is considered the perfect ratio of 3:1.*

Hempseed oil is a perfect alternative to other conventional oils for use in salads, marinades, sautés and dipping sauces. It is also an excellent emollient and can be easily formulated into personal care products such as soaps, shampoos, skin creams and lotions.

CHARACTERISTIC	**Unit**	**Specifications**
Appearance	Compares to standard	Clear, bright oil
Odor	Compares to standard	Virtually none
Color (Lovibond 5 $^1/_4$" cell)	Lovibond 5 $^1/_4$" cell	4.0 red, 40 yellow, 0 2 blue maximum
Refractive Index @ 40° C	N/A	1.4690 – 1.4720
Free Fatty Acid (% as oleic)	%	0.1 maximum
Acid Value	mg KOH/g	0.5 maximum
Iodine Value	g I_2/100 g	145 – 165
Peroxide Value	meq/kg	5 maximum
Moisture	%	0.1 max
Fatty Acid Profile (major acids):		
C16:0 Palmitic	%	5 – 12
C16:1 Palmitoleic	%	0.5 maximum
C18:0 Stearic	%	1.0 – 4.5
C18:1 Oleic	%	10 – 16
C18:2 Linoleic	%	45 – 65
C18:3 Linolenic	%	14 – 30
C18:3 Gamma Isomer (GLA)	%	1.0 minimum
C20:0 Arachidic	%	2 maximum
C20:1 Eicosenoic	%	1 maximum
C22:0 Behenic	%	1 maximum

Attachment III



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Composition, Properties, and Health Benefits of Hemp (*Cannabis sativa* L.) Seed Oil

Report by Phytomedics Inc.

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ABBREVIATIONS. AA, arachidonic acid; CBD, cannabidiol; CBDA, cannabidiolic acid; DGLA, dihomogamma linoleic acid; DHA, docosahexaenoic acid; EPA, eicosapentaenoic acid; GLA, γ-linolenic acid; LA, linoleic acid; LNA, α-linolenic acid; THC, Δ^9-tetrahydrocannabinol.

ABSTRACT. The fatty acid and natural product content of hemp seed oil was analyzed by GC-MS and LC-MS. The presence of linoleic acid (LA) and α-linolenic Acid (LNA) were confirmed in their previously reported ratio of 3:1 LA:LNA. The presence of β-caryophyllene (740 mg/L), myrcene (160 mg/L), β-sitosterol (100-148 g/L) and trace amounts of methyl salicylate was observed in the oil which had not been previously reported. Trace amounts of cannabidiol (CBD) were also detected. Bioassays were performed with the oil to determine its effectiveness as an antimicrobial agent. Some bioactivity was observed during the primary screening.

INTRODUCTION

Hemp (*Cannabis sativa* L.) seed oil is valued primarily for its nutritional properties as well as for the health benefits associated with it. Although its fatty acid composition is most often noted, with oil content ranging from 25-35%, whole hemp seed is additionally comprised of approximately 20-25% protein, 20-30% carbohydrates, and 10-15% fiber, along with an array of trace minerals (Deferne and Pate, 1996). With a complete source of all essential amino and fatty acids, hemp seed oil is a complete nutritional source. In addition, constituents exist within the oil that have been shown to exhibit pharmacological activity (Deferne and Pate, 1996), (Erasmus, 1999).

Hemp seed oil contains linoleic (LA) and α-linolenic acid (LNA) as its major omega-3 and omega-6 fatty acids, respectively. These fatty acids comprise the most desirable contents of the oil, especially due to the ratios in which they exist. The 3:1 ratio of LA to LNA is alleged to be optimal for nutrition (Deferne and Pate, 1996), (Callaway, Tennila & Pate, 1996), (Erasmus, 1999). The additional presence of gamma-linolenic acid (GLA) in hemp seed oil ultimately makes its nutritional value superior to most comparable seed oils. The myriad of benefits reported to be attributable to omega-3 fatty acids include anticancer, anti-inflammatory, and antithrombotic properties. In addition, dietary omega-3 fatty acids help to increase general metabolic rates and promote the burning of fat (Erasmus, 1999), (Simopoulos, 1994).

Cannabidiol (CBD) has been found to be present in hemp seed oil as well. Although not explicitly produced within the seed, traces of cannabinoid contamination have been reported to result from the pressing of the oil (Grotenhermen et al. 1998). Reports of cannabinoid contamination have been focused primarily on delta-9-tetrahydrocannabinol (THC) with THC levels in oil reported at up to 50 ppm (Grotenhermen, Karus & Lohmeyer, 1998). The production and storage of both CBD and THC occur in the glandular structures of the plant and the concentrations of CBD are typically much higher than THC in most fiber and oil varieties of hemp. Therefore, it can be assumed that the concentration of CBD as a contaminant in the oil would be greater than the concentration of THC which has been reported in the literature. The presence of CBD is significant because it has documented anticonvulsive, anti-epileptic, and antimicrobial properties (Karler and Turkanis, 1973), (Ferenczy, Gracza & Jakobey, 1958). Although the levels of CBD within the oil are typically small, many health benefits may still be gained from its presence.

Although previously identified only in the essential oils of the Cannabis plant (Hendriks, Malingre, Batterman & Bos, 1978), terpenoid compounds have been identified as being present within the seed oil. Health benefits may be gained from their presence even at concentrations similar to that of CBD. As is the case with CBD, the presence of these terpenes is most likely the result of contamination from glandular hairs during oil processing. Nevertheless, the major terpenes identified have been cited as having anti-inflammatory, anti-allergenic, and cytoprotective pharmacological properties (Tambe, Tsujiuchi, Honda, Ikeshiro, & Tanaka, 1996).

While many studies exist which base the nutritional value of hemp seed oil primarily on its fatty acid content, there are other constituents which are contained within the oil that possess beneficial properties as well. Natural products such as β-sitosterol and methyl salicylate complement the nutritious value of hemp seed oil and increases its effectiveness as a functional food. Even though the existing data on hemp seed oil clearly demonstrates its nutritional value, these additional compounds do add a marketable value, and need to be examined further for additional beneficial qualities and characterizations.

MATERIALS AND METHODS

GC-MS Analysis of Hemp Oil Constituents

The analysis of the total fatty acid composition of hemp oil was performed using standard techniques and reagents. The hemp oil samples (40 µL) were saponified and methylated as described by Sasser, 1990. The samples were manually injected in the splitless mode into a gas chromatograph (model 5890, Hewlett-Packard)/mass spectrometer (model 5971, Hewlett-Packard) equipped with a 30-m X 0.25 mm DB-5MS fused silica capillary column (J&W Scientific, Folsom CA). Chromatographic parameters were as follows: injection temperature at 280°C, initial oven temperature at 50°C for 5 min followed by a ramp at 5°C/ min to 280°C. Fatty acid standards of palmitic, oleic, stearic linolenic, linoleic and gamma-

linolenic acids (Sigma, Saint Louis, MO) were processed and analyzed simultaneously for purposes of identification and quantification. Hemp oil samples were typically diluted in hexane 1:1 for natural products analysis. The concentrations of myrcene and β-caryophyllene within the oil were based on standards obtained from Sigma, St. Louis, MO. The trace amounts of methyl salicylate were identified by GC retention time and mass fragmentation pattern.

LC-MS Analysis of Hemp Oil Constituents

Unmethylated total fatty acids and free fatty acids were also analyzed using a Waters Integrity® LC-MS system consisting of a 616 pump, 717 plus autosampler, 996 photodiode array detector and a Thermabeam® EI-MS detector. The Thermabeam Mass Detector operates with standard electron impact ionization energy of 70 eV and operated in the scanning mode from 45 to 700 *m/z* producing library searchable spectra. Spectral data was managed by the Millennium v. 2.21 LC-MS software. A Waters semi-microbore Nova Pak C_8 column (2mmX150mm) was equilibrated with 0.5% acetic acid:acetonitrile (95: 5, v/v) with a flow of 0.25 mL/min. After injection, a gradient to a final solvent composition of 5:95, v/v, was established over 25 min. The solvent composition will then be returned to initial over 2 min and equilibrated for 15 min prior to subsequent injections. Mass fragmentation pattern searches using the Wiley® registry for mass spectral data, 6th edition were used for the identification of the fatty acid and chemical constituents of the oil in addition to the use of chemical standards. Analysis of natural products by LC-MS was performed with hemp oil diluted in isopropanol. Concentrations of β-sitosterol, α/γ-tocopherol, and CBD were then quantified on the basis of standards supplied by Sigma, St. Louis, MO.

Activity Bio-Assay

Assay screenings were performed using hemp seed oil diluted into several solvents. Sample solutions were prepared using 500 µL hemp oil diluted 1:5 into either 80% methanol or 100% methanol, or 1:1, 1:3, and 1:5 in hexane (Sigma, St. Louis). Complete solubility was achieved exclusively in hexane and emulsions were formed with other solvents. The oil sample emulsions of 80% and 100% methanol were vortexed for 10 seconds and then centrifuged at 10,000g and 21° C for 5 minutes to separate into distinct layers. The supernatant layer was then tested for activity.

The oil/solvent solutions were evaluated for their ability to inhibit the growth of organisms representing the major pathogenic classes: *Aspergilus niger* (mycelium-forming fungi) *Escherichia coli* (Gram-negative)*Staphyllococcus aureus* (Gram-positive), *Saccharomyces cerevisiae* (yeast, single cell fungi) and *Pseudomonas aeruginosa*. Bacterial (*E. coli* and *S. aureus*) cultures were cultivated and maintained on solid agar medium (LB Agar, Miller). Before performing each assay, bacteria was transferred into liquid medium and cultivated for 12 hours at 37 °C on a shaker. Preliminary studies show that this cultivation results in cell density values of 10^5-10^6, which is sufficient for antimicrobial activity evaluation. *S. cerevisiae* was cultivated and maintained on potato dextrose medium. Prior to testing, yeast cells were transferred into liquid medium and cultivated for 48 hours at 30 °C on a shaker

Sterile, plastic microplates containing 24 wells (4x6) were used for testing. 2 mL of freshly sterilized LB agar medium (for antibacterial tests), or 2 mL of potato dextrose agar (for antifungal tests), were dispensed in each well of the 24-well sterile microplates under sterile conditions at a temperature of 40–50 °C. 10 µL aliquots of oil/solvent samples were injected into each well in triplicate. The fourth well being used as a control with 10 µL of solvent. This was repeated for each microorganism for a total of 25 (5x5) rows of testing. The plates were left open for a few minutes in the laminar flow hood, so that the solvent of the 10 µL sample partly diffused and partly evaporated from the surface, after which 30 µL of the previously prepared bacterial suspension, or fungal spore suspension was plated on the agar surface of each well. Plates were then closed, marked, and transferred in an incubator for 24 hours at 30 °C. After incubation, the plates were examined for cells/spores growth inhibition zones.

A smaller variety of microorganisms were used in the secondary screening, as the primary screening eliminated possible activity against certain microbes.
The oil/solvent solutions were re-tested for activity against *Staphyllococcus aureus*, *Escherichia coli* and *Saccharomyces cerevisiae* using the same methods as described in the primary screening.

RESULTS & DISCUSSION

I. FATTY ACIDS IN HEMP OIL

The hemp seed oil used in this study was pressed from Canadian grown seed of the French variety Fedora-19 and was provided by CGP Canada, Ltd. The results of fatty acid analysis are shown in Table 1. These results further strengthen previous reports that the relative ratios and composition of hemp oil fatty acids are ideal for human nutrition.

Benefits of Essential Fatty Acids

While there are many sources for omega fatty acids in the diet, hemp seed oil is exceptionally rich in these compounds, which are usually present in the nutritionally optimal ratio of 3:1 (omega-6:omega-3) LA to LNA (Erasmus, 1999). As shown in Table 1, LA concentrations ranged from 52-62% of total fatty acid composition while LNA concentrations ranged from 12-23%. The range of concentrations of fatty acids results from the natural variation of individual samples of the Fedora hemp oil being tested. Several factors, including processing and storage methods, as well as age of the samples being tested, could contribute to the variability of the fatty acid profile.

As a result of the change in dietary habits within the past century, the intake of *trans* -fatty acids has increased dramatically. Studies have shown conclusively that *trans* -fatty acids increase total cholesterol levels and diminish the levels of 'good' high density lipoprotein (HDL). By supplementing the diet with high levels of unsaturated *cis* -fatty acids, some of these negative effects can be reversed (Erasmus, 1999). With respect to modern diets, the amount of LA consumed compared to the amount of LNA consumed has increased exceptionally in the past 100-150 years (Simopoulos, 1994). This disparity has disrupted the proper balance of dietary essential fatty acids that is considered nutritionally optimal. In addition to the lack of these essential fatty acids in the diet, factors such as stress and disease weaken the enzymatic activity that promotes the conversion of LA to GLA (Deferne and Pate, 1996). Therefore, a supplementation of LA can be helpful to alleviate this potential deficiency.

In an ideal diet, the daily consumption of fats should not exceed 15-20% of total caloric intake. Approximately one third of these fats should be the essential fatty acids in their proper ratio. For a 2500 calorie/day diet, LA intake should be 9-18 grams/day, and LNA intake should be 6-7 g/day (Erasmus, 1999). This goal can easily be accomplished through the daily consumption of 3 to 5 tablespoons of hemp oil. Although these are the ideal amounts to maintain a healthy, balanced diet, certain stresses to the body warrant increased consumption of essential fatty acids, particularly the omega-3's such as LNA.

Omega-3 fatty acids have been reported to have an inhibitory effect on cancer and tumor growth. Increased consumption of omega-3 fatty acids have not been shown to exhibit any negative side effects, but their beneficial qualities have been repeatedly confirmed. In addition to their anticancer properties, omega-3 fatty acids have been shown to lower blood pressure and blood cholesterol levels, help normalize fat metabolism and decrease insulin dependence in diabetics, increase overall metabolic rate and membrane fluidity, and exhibit anti-inflammatory properties, specifically with regard to relieving arthritis (Erasmus, 1999). The benefits of omega-3 fatty acids are not only present when taken in large quantities but the regular intake of recommended levels (2-2.5% of caloric intake/day) can be sufficient to provide many of its nutritional qualities.

The essential role of LA and LNA in the human diet is related to both the intermediary and end products that they become through several biochemical pathways. The fatty acid metabolism of LA and LNA is elucidated in Figure 1. LA is metabolized to GLA and subsequently arachidonic acid (AA). LNA is metabolized to both eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) (Simopoulos, 1994). EPA and AA are metabolized by the body into eicosanoids. These compounds ultimately become the prostaglandins which affect such varied functions as blood clotting, inflammation response, and immunoregulation (Erasmus, 1999).

During the synthesis of prostaglandins from AA and EPA, there is a biochemical competition within the cell membrane (Simopoulos, 1994). The AA has a tendency to move out of the cell membrane and form type 2 prostaglandins. EPA tends to promote the retention of AA within cell membranes, thereby preventing the formation of the unwanted type 2 prostaglandins (Erasmus, 1999). When the ratio of the

initial starting compounds is shifted in favor of LA, however, it becomes more difficult for the products from LNA to sufficiently promote the retention of AA within the cell membrane. The resultant increase in type 2 prostaglandin production leads to increased platelet aggregation and inflammation (Erasmus, 1999). The benefits of having the proper ratios of fatty acids, with respect to the metabolized products of LA and LNA, are the production of the proper amounts of prostanoids and leukotrienes which have antithrombotic, antivasoconstrictive, and anti-inflammatory properties (Simopoulos, 1994).

II. NATURAL PRODUCTS IN HEMP OIL

The results of the natural products analysis of the hemp oil are shown in Table 1. These results suggest that several natural products, such as cannabidiol, β-caryophyllene, myrcene, β-sitosterol, α/γ-tocopherol, and methyl salicylate may confer further health benefits to hemp oil in addition to fatty acids.

1. Cannabidiol

Pharmacological Properties of Cannabidiol

Cannabidiol (CBD) has been shown to possess several desirable pharmacological properties which are exhibited in absence of the psychoactive properties of THC, (Karler and Turkanis, 1981) which are usually associated with the cannabinoids. Although the levels of CBD detected in the oil were low at 10 mg/kg, its presence could still provide some benefit. CBD has been reported to reduce tremors in dystonic movement disorders with minimal side effects (Consroe et al., 1986). Patients receiving doses of CBD ranging from 100-600 mg/day had tremor reductions of 20-50%. (Consroe et al., 1986). The anticonvulsant and anti-epileptic activity of CBD has also been well documented (Karler et al. 1973), (Karler and Turkanis, 1981). CBD has been found to be relatively selective with respect to the central nervous system (CNS), in contrast to THC (Karler and Turkanis, 1981). Its anticonvulsant activity is on the same order of magnitude of THC, but unlike THC, it lacks psychoactivity. CBD's added efficacy as an anti-epileptic, without the associated side effects of psychoactivity, give it great pharmacological potential.

Analgesic and anti-inflammatory potential has been reported in animal studies with CBD as well (Formukong et al., 1988). CBD has been shown to inhibit both the induction of phenyl benzoquinone (PBQ) induced writhing and tetradecanoyl phorbol-acetate (TPA) induced erythema, (Formukong et al., 1988). The mechanism by which CBD achieves its anti-inflammatory properties is possibly related to its effect on arachidonate metabolism (Formukong et al., 1988).

Antimicrobial activity has also been reported for CBD. Specifically, CBD has been shown to inhibit the growth in Gram-positive bacteria such as *Streptomyces griseus* and *Staphylococcus aureus* (Ferenczy et al. 1958). These organisms are particularly sensitive to extracts of Cannabis in slightly acidic culture medium even at dilutions as low as 5ppm.

Biosynthesis

It is generally accepted that the biosynthetic pathway of the cannabinoids begins with the condensation of geranyl pyrophosphate with olivetolic acid (Clarke, 1981), (Turner et al., 1980). As shown in Figure 2, the initial cannabinoid formed is cannabigerolic acid, which in turn is converted into cannabidiolic acid, tetrahydrocannabinolic acid, and ultimately cannabinolic acid. Several other cannabinoids are also formed in smaller quantities from side reactions. It has been reported that transient propyl and methyl forms of the cannabinoids exist as well as the predominant pentyl forms (Clarke, 1981).

The chemical structures of the cannabinoids in Figure 2 are depicted as their acid forms. These molecules do not possess any psychoactivity until they are decarboxylated. Decarboxylation occurs spontaneously or with the addition of heat (Clarke, 1981). The biosynthesis of the cannabinoids proceeds through the pathway with the molecules in their acid forms. It is the metabolism of these acid forms which will ultimately determine which cannabinoids will accumulate (Clarke, 1981). The ratio of these specific cannabinoids is used to determine the gross chemotype of particular hemp plants. Evidence exists which shows the relation of chemotype to latitude of cultivation.

Through experimentation and observation, it has been determined that increasing ultraviolet (UV) radiation accelerates the "ripening" process of Cannabis (Turner et al.). In tropical latitudes, Cannabis specimens tend to complete the ripening process with nearly complete conversion of CBD into THC. This is contrasted by Cannabis which is cultivated at more temperate latitudes where there is a higher proportion of CBD to THC within the plants. The increasing amounts of UV light at latitudes approaching the equator tends to accelerate production of THC from CBD, most likely due to an evolutionary advantage for THC accumulation as a protective agent of UV light (Pate, 1994).

The cultivation of modern day industrial hemp crops in more northern latitudes will show a gross chemotype of high CBD/ low THC. With these "unripe" varieties, it will be possible to take advantage of the relatively high levels of CBD as compared to THC, and exploit the many benefits of CBD without risk of psychoactivity. The oil which was subjected to investigation here was Canadian grown. It has significant concentrations of CBD but no detectable THC. These results are consistent with the predicted cannabinoid content of northern-grown plants.

2. β-sitosterol

Another component of hemp seed oil with several reported activities is β-sitosterol. Although studies have primarily demonstrated the efficacy of β-sitosterol in reducing hypercholesterolemia, additional antiviral, antifungal, and anti-inflammatory properties have been studied and observed (Malini and Vanithakumari, 1990).

Plant sterols have been known to affect plasma cholesterol levels by blocking cholesterol absorption through crystallization and coprecipitation (Mattson, Grundy, and Crouse, 1982). Within the intestinal lumen, phytosterols reduce cholesterol solubility by excluding it from micelles, thereby preventing its absorption. In addition, competition exists between the sterols and cholesterol for uptake into the intestinal mucosa (Lees, Mok, Lees, McCluskey, and Grundy, 1977). A quantitative representation of this can be seen in human studies. Patients given 500 mg of cholesterol daily in their diets in addition to 1 g of β-sitosterol showed decreased cholesterol absorption. Mean reduction levels were 42%, demonstrating the efficacy of β-sitosterol even at low concentrations (Mattson et al., 1982). As shown in Table 1, sterol concentrations based on β-sitosterol were measured in sufficient quantities at 100-148 g/L. Although β-sitosterol was the predominant sterol, other minor sterols may have contributed to this measurement. At these levels, many of β-sitosterol's beneficial qualities will be obtainable.

β-sitosterol seems to be particularly effective in cholesterol uptake inhibition, especially when delivered through dietary fats (Lees et al., 1977), (Mattson et al., 1982). No appreciable decreases in efficacy were observed, even with long-term administration (Lees et al., 1977). In addition, lack of toxicity and little, or no side effects have been attributed to β-sitosterol, making it an attractive option for long-term cholesterol reducing therapy (Lees et al., 1977), (Mattson et al., 1982).

Although not studied as extensively as its hypocholesterolemic properties, relevant antiviral and anti-inflammatory activities of β-sitosterol have been shown. Isolated ethanolic extracts of *Hedychium spicatum* containing β-sitosterol showed anti-inflammatory activity (Sharma, Shukla, and Tandon, 1975). When purified, β-sitosterol fractions from *Artemisia annua* showed upwards of 80% virus inhibitory activity against tobacco mosaic virus (Abid Ali Khan, Jain, Bhakuni, Zaim, and Thakur, 1991).

3. Tocopherols

Antioxidant properties of tocopherols have been known and exploited for some time. Traditional supplementation of tocopherols has primarily focused on its α form. Many plants however, including hemp, tend to have significantly higher levels of γ-tocopherol. Although both exhibit antioxidant activity, their differing metabolic paths confer other specific activities to their respective isomeric forms.

α-Tocopherol is the primary (usually exclusive) tocopherol in formulated vitamin E supplements. It is preferentially secreted into plasma as opposed to γ-tocopherol which tends to be found in the intestine (Stone & Papas, 1997). It is α-tocopherol's concentration in the plasma that gives it properties other than that of an antioxidant. α-Tocopherol may induce increased membrane fluidity through intercalation

between fatty acyl chains in the membrane bilayer (Berlin, Bhathena, Judd, Padmanabhan, Nair, Peters, Bhagavan, Ballard-Barbash, and Taylor, 1992). Data suggests that there is a direct correlation between increased fluidity and α-tocopherol content in the membrane (Berlin et al., 1992).

The biological activity of α-tocopherol tends to be significantly higher than γ-tocopherol as a result of its greater affinity to be secreted by the liver into very-low density lipoproteins (Stone & Papas, 1997). This increased bioactivity does not however make α-tocopherol a more effective antioxidant; γ-tocopherol inhibits phosphatidylcholine-hydroperoxide formation more effectively at low peroxynitrite concentrations than does α-tocopherol (Wolf, 1997). γ-Tocopherol has been shown to have significant antioxidant effects *in vitro* even at concentrations less than 50 ppm (Lampi, Hopia, & Piironen, 1997). In addition, γ-tocopherol is overall more effective in protecting against coronary heart disease, as compared to α-tocopherol supplementation (Wolf, 1997).

Perhaps the most interesting activity of γ-tocopherol which has not yet been widely studied, is its ability to act as an anticancer agent, specifically with respect to colon cancer. Because γ-tocopherol is secreted via the bile into the intestine and fecal material, it can inhibit lipid peroxidation and reduce the formation of mutagenic peroxidation products in the bowel (Stone & Papas, 1997). Ultimately, by being excreted into the colon, as opposed to being active in the plasma, γ-tocopherol is able to minimize DNA damage caused by reactive nitrogen oxide species (Stone & Papas, 1997).

4. Terpenes

The presence of several terpenes were confirmed in the seed oil, the most abundant of which were β-caryophyllene and myrcene which were found at 740 mg/L and 160 mg/L, respectively (Table 1). The terpene compounds, in general, are primarily found in the essential oil of Cannabis rather than in the seed oil (Hendriks et al., 1978) as a result of their production in the glandular structures on the aerial portions of the plant. These compounds are a component of the characteristic aroma of Cannabis and may impart some of these properties to the seed oil. Additional benefits may be provided to the oil as well.

Some previously noted pharmacological properties of β-caryophyllene would include anti-inflammatory and cytoprotective activities which may too be active in the seed oil. In addition, it has been reported that myrcene exhibits antioxidant properties (Duke, 1999). The presence of β-caryophyllene and myrcene, even if only present as contamination components, add beneficial value to an already nutritionally important food product.

5. Methyl salicylate (oil of wintergreen)

The medical benefits of plant salicylates have been enjoyed by people for centuries. Today aspirin or acetylsalicylic acid, a close relative of methyl salicylate, is one of the most widely used drugs in the world because of its antipyretic, anti-inflammatory and analgesic properties. Once injected, methyl salicylate can be hydrolyzed to salicylic acid, a common active ingredient of aspirin and most other salicylates. Thus, pharmacological effects of methyl salicylate are similar to those of aspirin. Also, millions of people regularly take low doses of salicylates (aspirin) to reduce the risk of heart attacks, strokes and cancer. Methyl salicylate deserves particular attention as a beneficial component of hemp oil, even if present in trace quantities.

III. HEMP OIL BIO-ASSAY

Because of the relatively complex macrocomposition of hemp seed oil, numerous compounds within the oil have the potential to exhibit antibacterial and/or antimicrobial activity. Samples of the oil were diluted in various solvents and tested against several microorganisms, including bacteria and fungi.

A screening with an 80% methanol supernatant showed the ability of a component of the hemp oil to inhibit the growth of yeast in 2 of the 3 wells tested. It is unclear, however, if this activity is sufficient to characterize a constituent of the hemp oil as a significant inhibitor of yeast growth. The hemp oil dissolved 1:1, 1:3, and 1:5 in hexane without an initial extraction into other solvents also showed some bioactivity, significantly more so than the 80% methanol supernatant sample. There were clear zones of growth inhibition on the agar in the three samples of hemp oil diluted with hexane which would indicate a more significant inhibition of yeast growth.

Secondary screenings performed to support the results of the initial assays were inconclusive. The growth inhibition of yeast that was exhibited during the first screening did not yield the same results upon replication. Factors such as the concentration of antimicrobial compounds within the oil, or deterioration of the oil due to age could have played a role in the inability to replicate the initial results.

Even though it is unclear how significant the ability of hemp oil constituents to inhibit the growth of yeast is, some activity was detected which has never been previously reported in the literature. Therefore it is possible that the hemp seed oil may have an antimicrobial component, separate from CBD, which specifically prevents the growth of yeast, an activity which has not been previously demonstrated.

Although the screenings that were performed could not demonstrate antibacterial properties within the oil, reports of antibacterial properties of CBD have been documented in the scientific literature. In previous experiments, CBD was found to inhibit the growth of Gram positive bacteria (Ferenczy et al., 1958). Previous reports of antibacterial activity with respect to CBD have primarily focused on CBD concentrates taken from the resin of the plant. Because CBD is a contaminant in the seed oil as a result of oil processing techniques, and not actually produced within the seed according to the literature, the levels of CBD in the oil are most likely to be too low to exhibit antibacterial properties. The precise quantification of the CBD will help to address this issue. It has been noted however that in previous screenings of CBD for antibacterial properties, there is a strong correlation between the plant's levels of cannabidiolic acid (CBDA) and antibacterial effectiveness (Radosevic, 1962). Plants which contained higher concentrations of CBDA displayed more pronounced antimicrobial activity. This also correlates with the observation that Cannabis plants from more northern latitudes have stronger antimicrobial activity than more tropical plants, most likely due to the specific cultivars' CBD/THC ratio.

SUMMARY

After detailed analysis of the macrocomposition of the hemp seed oil, several constutituents which have not previously been reported within the oil have been detected, along with the major fatty acid components.

Hemp seed oil is comprised almost entirely of fatty acids, with an essential fatty acid content of approximately 75%. As shown in Table 1, hemp oil is comprised primarily of LA and LNA in a 3:1 ratio. These results have been reported in the literature and were confirmed in this study. Other beneficial natural products such as β-sitosterol, which contributes hypocholesterolemic properties, and the tocopherols, which have both antioxidant and anticancer activities, are present in sufficient efficacious quantities. In addition, measurable amounts of terpenes, cannabinoids and phenolics were detected, including methyl salicylate which itself has many health benefits.

Table 1. Hemp Seed Oil Macrocomposition

Components	Reported (Deferne and Pate, 1996; Callaway and Laakkonen, 1996)	Results
Fatty Acids	(% w/w)	(% w/w)
Linoleic Acid (18:2ω6)	50-70	52-62
α-Linolenic Acid (18:3ω3)	15-25	12-23
Oleic Acid (18:1ω9)	10-16	8-13
Palmitic Acid (16:0)	6-9	5-7
Stearic Acid (18:0)	2-3	1-2
γ-Linolenic Acid (18:3ω6)	1-6	3-4
Eicosanoic Acid (20:0)	0.79-0.81*	0.39-0.79
Eicosenoic Acid (20:1)	0.39-0.41*	0.51
Eicosadienoic Acid(20:2)	0.00-0.09*	0.00
Natural Products		
Cannabidiol	nr	10 mg/kg
Δ^9-tetrahydrocannabinol	50 mg/kg**	nd
Myrcene	nr	160 mg/L
β-caryophyllene	nr	740 mg/L
β-sitosterol	nr	100-148 g/L‡
α-tocopherol	7-80 ppm †,††	tr
γ-tocopherol	710-870 ppm †,††	468 mg/L
Methyl salicylate	nr	tr

* as reported for variety FIN-314
** as reported by Grotenherman et al. (1998)
† as reported by Blade, (1997)
†† as reported by HYChem Corporation. Henry Yard, personal communication
‡ total sterol content measured as β-sitosterol
nr – not reported in cold pressed oil
nd - not detectable (lower limits of detection could not be determined without THC standard)
tr - trace amounts

The reported health benefits of hemp seed oil, and especially the essential fatty acids, are well documented. When diets are supplemented with omega-6 and omega-3 fatty acids in the proper 3:1 ratio, numerous benefits to health are achieved, including but not limited to greater resistance to cancer, inflammation, and blood clotting. A general increase in metabolism and lower overall blood cholesterol levels have also been observed.

In addition to all of these positive health benefits associated with the use of hemp oil, there seems to be a complete lack of negative effects from its consumption. To date, there has been no reported cases of toxicity from the ingestion of hemp seed oil. Toxicity has also not been observed with any of the other constituents that were found as contaminants, which are primarily the cannabinoids.

One reason for the lack of negative side effects from excessive ingestion of hemp oil is specifically related to the ratio of LA:LNA. Because most oils do not contain the optimum ratio of omega-6 and omega-3 fatty acids, they tend to promote the accumulation of metabolic intermediates that in turn hinder fatty acid metabolism. The properly balanced hemp seed oil does not promote an over-accumulation of certain metabolic products and all of the fatty acid metabolic pathways have the necessary intermediates to work efficiently regardless of the quantities consumed.

The value of hemp seed oil is only beginning to be recognized in the marketplace. Its ideal fatty acid composition serves as only one of several potential beneficial qualities. A nutritionally complete food product that also exhibits several active pharmacological properties will undoubtedly have an appeal to a variety of potential markets and consumers. Although initially marketed to the natural foods consumer, the many benefits of hemp seed oil as an ideal food product and a nutritional supplement can be exploited providing interest to the mainstream consumer as well.

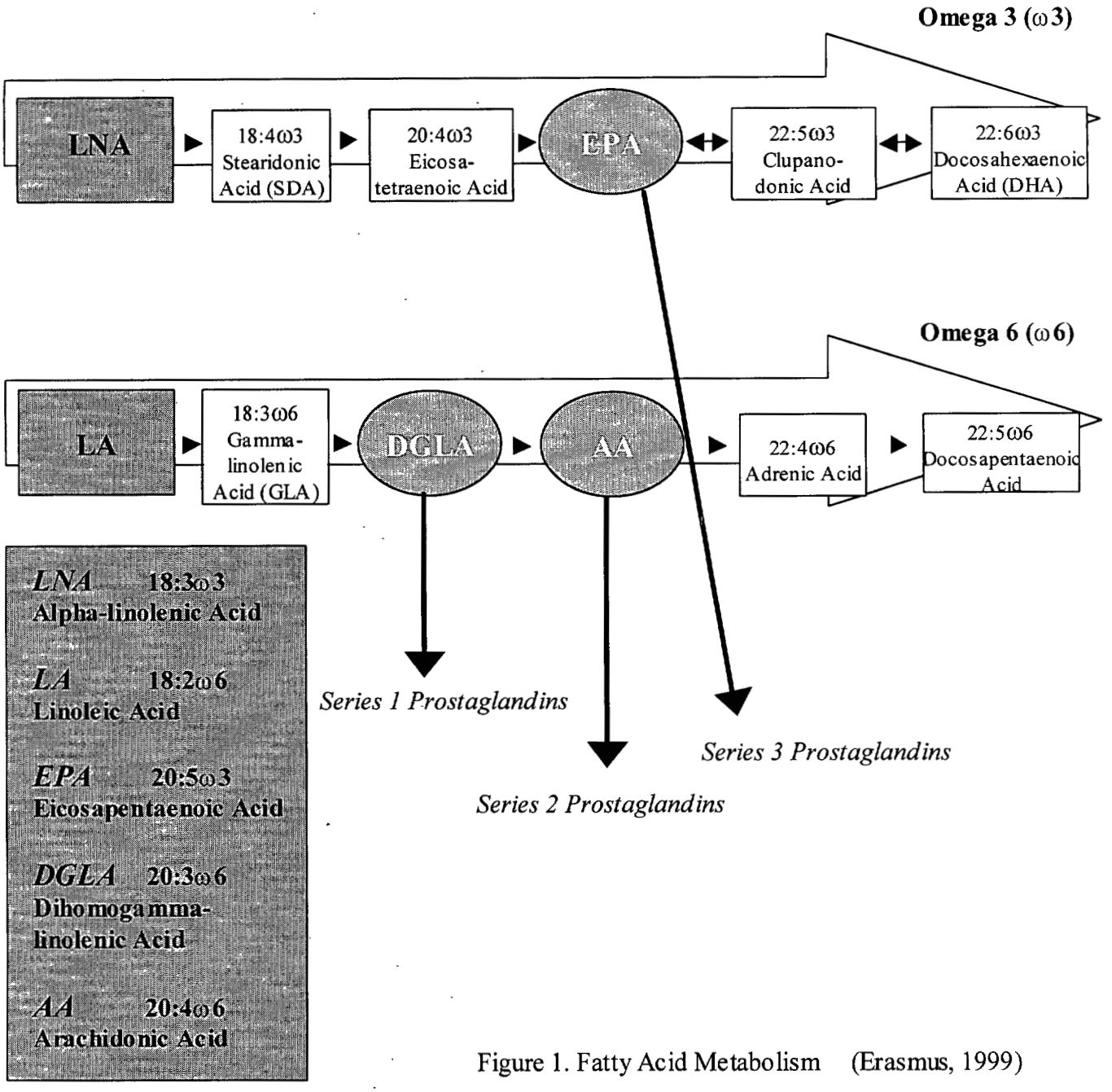

Figure 1. Fatty Acid Metabolism (Erasmus, 1999)

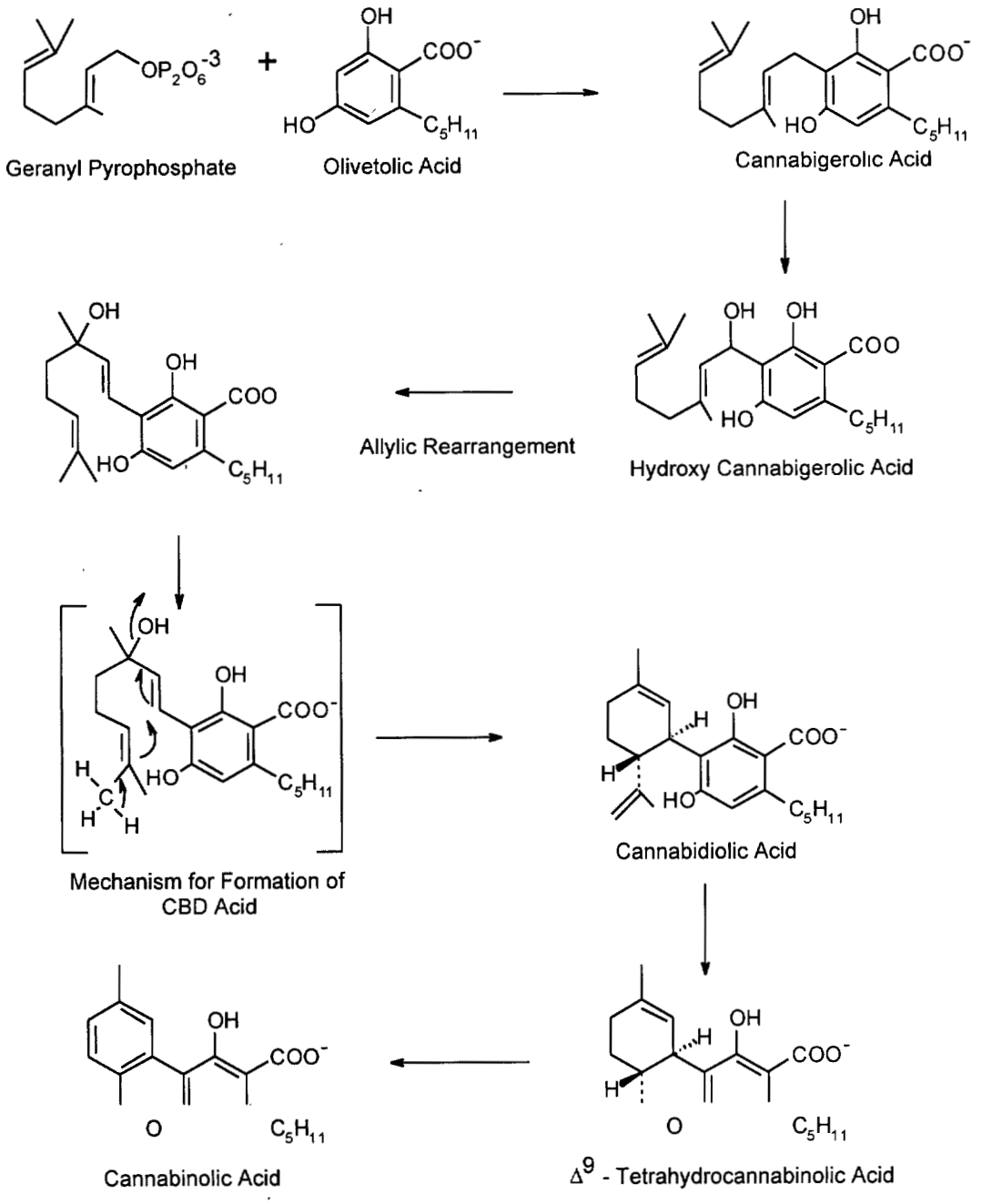

Figure 2. Cannabinoid biosynthetic pathway. (Clarke, 1981)

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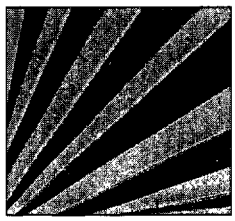

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2000 JAN 19 P 12:07

Paulette M. Gaynor, Ph.D.
Division of Petition Control, HFS-215
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

January 13, 2000

Re: GRAS Notice (GRN) No. 000035

Dear Dr. Gaynor,

As per our telephone conversation, enclosed please find copies of four references that you requested. If you have any additional questions please feel free to contact me directly at 917-748-6071 or via e-mail at dushenkov@aol.com.

Sincerely,

Slavik Dushenkov, Ph.D.
Executive Vice President

Enc:

1. 1895 Yearbook of the United States Department of Agriculture (pgs 198-199) Publish date: 1896 Author: Gilbert H. Hicks; Assistant, Division of Botany, U.S. Department of Agriculture
2. The provisions of Executive Order 10480 of Aug. 14, 1953, appear at 18 FR 4939, 3 CFR, 1949-1953 Comp., p. 962
3. Letter, Department of Agriculture Office of the Secretary, Mr. Dan Glickman, June 19, 1995, re: Ms. Debby Moore President, Kansas Environmentalists for Commerce in Hemp
4. Letter, Office of Consumer Education, FDA, CFSAN, Lyn Goosens, MPH, RD, September 9, 1999, re: Hempseed Oil Safety as Food

000035

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1895 Yearbook of the United States Department of Agriculture

(pgs 198-199) Publish date: 1896

Author: Gilbert H. Hicks; Assistant, Division of Botany, U.S. Department of Agriculture.

OIL-PRODUCING SEEDS: HEMP

Hempseed oil comes from an annual plant of the nettle family (Cannabis sativa), which is indigenous in central Asia and the East Indies. It is cultivated in India, Persia, China, North America, Germany, and, more than anywhere else, in Russia. It grows from 4 to 8 feet high in waste and cultivated ground. The odor of the fresh leaves sometimes produces headaches, while the celebrated narcotic, hashish, is prepared from a gelatinous resin contained in the leaves and stems. The latter also furnish the well-known fiber used for cloth and cordage.

The male and female flowers are borne on different plants. The nut-like fruits, commonly called seeds, are used in great quantities in bird food. They are nearly egg-shaped in outline, flattened at the margins. Color, dark gray, with fine, net-like, whitish markings on the smooth and shiny surface. Each fruit is completely filled with the seed proper, which is of the same shape and about 4mm. long by 3 mm. wide and 2 to 3 mm. thick. The seeds contain no endosperm, but are filled with a whitish embryo which yields 30 to 35 per cent of a peculiar-smelling, mild-tasting oil, greenish yellow when freshly pressed, becoming brownish yellow with age. Hempseed oil is used to a considerable extent in the preparation of paints and varnishes, although it does not dry as readily as linseed oil. In Europe it enters largely into the composition of soft soaps. Sometimes it is used in the Old World as an illuminant and, rarely, for food.

Hemp will thrive in most parts of the United States, and is said to

produce from 20 to 40 bushels of seed to the acre, worth about $2.50 per 100 pounds. With extra good care and soil the yield may reach 50 to 60 bushels. The seed should be planted in drills, early in April in the South, two weeks later in the North. The young plants are thinned out when a foot high, and must be kept free from weeds. The male plants should be pulled as soon as they have shed their pollen, so as to allow the seed-producing plants plenty of room and all of the available soil food.

Hemp should be harvested promptly as soon as the seed begins to drop, which always takes place after a sharp frost, if not before. The seeds scatter easily; hence hemp should be cut early in the morning when the dew is on, and great care exercised to prevent waste. When cut, hemp should be set up in loose shocks to dry, a sheet being placed under each one, and some protection afforded from birds, as they are fonder of this seed than almost any other. Drying is completed by spreading the plants out on a tight barn floor, where they are thrashed by hand.

Hempseed, notwithstanding its oily content, loses its germinative power quickly, usually by the end of one year; hence only fresh seed should be sown. Neither cracked nor dull-looking seed will germinate well. Hemp culture in America is mostly confined to Kentucky and Missouri, principally the former State. The value of hemp for fiber, birdseed, and oil would seem to make its cultivation a very profitable one.

Executive Order 10480--Further providing for the administration of the defense mobilization program

Source: The provisions of Executive Order 10480 of Aug. 14, 1953, appear at 18 FR 4939, 3 CFR, 1949-1953 Comp., p. 962, unless otherwise noted.

Cross reference: Section 3 of Executive Order 11725 of June 27, 1973, 38 FR 17175, 3 CFR, 1970-1975 Comp., p. 779, which was revoked by Executive Order 12148 of July 20, 1979, Chapter 44, transferred certain functions under Executive Order 10480 to the Administrator of General Services.

By virtue of the authority vested in me by the Constitution and laws of the United States, including the Defense Production Act of 1950, as amended (50 U.S.C. App. 2061 et seq.), and as President of the United States and Commander in Chief of the armed forces of the United States, it is hereby ordered as follows:

Part I. General Direction of Program

Section 101. (a) The Director of the Federal Emergency Management Agency shall, on behalf of the President, coordinate all mobilization activities of the executive branch of the Government, including all such activities relating to production, procurement, manpower, stabilization, and transport. Every officer and agency of the Government having functions under the Defense Production Act of 1950, as amended, delegated, redelegated, or otherwise assigned thereto by or under the authority of the President after the date of this order (whether heretofore or hereafter acquired, or acquired by this order) shall perform the said functions subject to the direction and control of the Director of the Federal Emergency Management Agency.

(b) In carrying out the functions conferred upon him by this order, the Director of the Federal Emergency Management Agency shall, among other things:

(1) Perform the central programming functions incident to the determination of the production programs required to meet defense needs.
(2) Make determinations as to the provision of adequate facilities for defense production and as to the procedure and methods followed by agencies of the Government with respect to the accomplishments of defense production programs.
(3) Be the certifying authority for the purposes of and within the meaning of subsections (e) and (g) of Section 124A of the Internal Revenue Code, as added by section 216 of the Revenue Act of 1950, approved September 23, 1950.
(4) Issue such directives, consonant with law, on policy and program to officers and agencies of the Government for execution by them as may be necessary to carry out the functions assigned to him by this order, and resolve interagency issues which otherwise would require the attention of the President.
(5) Report to the President from time to time concerning his operations under this order.

[Sec. 101 amended by EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Sec. 102. [Revoked]

[Sec. 102 revoked by EO 10773 of July 1, 1958, 23 FR 5061, 3 CFR, 1954-1958 Comp., p. 416]

Part II. Priorities and Allocations

Sec. 201. (a) The functions conferred upon the President by Title I of the Defense Production Act of 1950, as amended, are hereby delegated to the Director of the Federal Emergency Management Agency, who shall, in carrying out the said functions, provide by redelegation or otherwise for their performance, subject to the provisions of section 101 of this order, by

(1) The Secretary of the Interior with respect to petroleum, gas, solid fuels and electric power.
(2) The Secretary of Agriculture with respect to food and with respect to the domestic distribution of farm equipment and commercial fertilizer.
(3) The Commissioner of the Interstate Commerce Commission who is responsible for the supervision of the bureau which administers the car-service functions of the Commission as set forth in paragraphs 10 to 17, inclusive, of section 1 of the Interstate Commerce Act, as amended with respect to domestic transportation, storage, and port facilities, or the use thereof, but excluding air transport, coastwise, intercoastal, and overseas shipping.
(4) The Secretary of Commerce with respect to all other materials and facilities.

(b) Findings made under or pursuant to and for the purposes of section 101(b) of the Act shall not be effective until approved by the Director of the Federal Emergency Management Agency.

[Sec. 201 amended by EO 10537 of June 22, 1954, 19 FR 3807, 3 CFR, 1954-1958 Comp., p. 195; EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Part III. Expansion of Productive Capacity and Supply

Sec. 301. The Department of Defense, the Atomic Energy Commission,1 the Department of Commerce, the Department of the Interior, the Department of Agriculture, the General Services Administration, and the National Aeronautics and Space Administration, in this Part referred to as guaranteeing agencies, each officer having functions delegated to him pursuant to section 201(a) of this order, and each other agency of the Government having mobilization functions, shall, within areas of production designated by the Director of the Federal Emergency Management Agency, develop and promote measures for the expansion of productive capacity and of production and supply of materials and facilities necessary for the national defense.

[Sec. 301 amended by EO 10819 of May 8, 1959, 24 FR 3779, 3 CFR, 1959-1963 Comp., p. 352; EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Sec. 302. (a) Each guaranteeing agency is hereby authorized, in accordance with section 301 of the Defense Production Act of 1950, as amended, subject to the provisions of this section, in order to expedite production and deliveries or services under Government contracts, and without regard to provisions of law relating to the making, performance, amendment, or modification of contracts, to guarantee in whole or in part any public or private financing institution (including any Federal Reserve Bank), by commitment to purchase, agreement to share losses, or otherwise, against loss of principal or interest on any loan, discount, or advance, or on any commitment in connection therewith, which may be made by such financing institution for the purpose of financing any contractor, subcontractor, or other person in connection with the performance of any contract or other operation deemed by the guaranteeing agency to be necessary to expedite production and deliveries or services under Government contracts for the procurement of materials or the performance of services for the national defense, or for the purpose of financing any contractor, subcontractor, or other person in connection with or in contemplation of the termination, in the interest of the United States, of any contract made for the national defense; but no small business concern (as defined in section 714(a)(1) of the said Act) shall be held ineligible for the issuance of such a guaranty by reason of alternative sources of supply.
(b) Each Federal Reserve Bank is hereby designated and authorized to act, on behalf of any guaranteeing agency, as fiscal agent of the United States in the making of such contracts of guarantee and in otherwise carrying out the purposes of section 301 of the said Act, as amended, in respect to private financing institutions.
(c) All actions and operations of Federal Reserve Banks, under authority of or pursuant to section 301 of the said Act, as amended, shall be subject to the supervision of the Board of Governors of the Federal Reserve System. Said Board is hereby authorized, after consultation with the heads of the guaranteeing agencies, (1) to prescribe such regulations governing the actions and operations of fiscal agents hereunder as it may deem necessary, (2) to prescribe, either specifically or by maximum limits or otherwise, rates of interest, guarantee and commitment fees, and other charges which may be made in connection with loans, discounts, advances, or commitments guaranteed by the guaranteeing agencies through such fiscal agents, and (3) to prescribe regulations governing the forms and procedures (which shall be uniform to the extent practicable) to be utilized in connection with such guarantees.

Sec. 303. The Administrator of General Services is hereby authorized and directed to purchase and make commitments to purchase metals, minerals, and other materials, for Government use or resale, as authorized by and subject to the provisions of section 303 of the Defense Production Act of 1950, as amended: Provided, That the Secretary of Agriculture may also exercise the said functions under section 303 of the said Act, as amended, with respect to food, and with respect to plant fibers (except abaca) not included in the definition of food to the extent that the procurement of such fibers involves the encouragement and development of sources of supply within the United States and its Territories and possessions.

Sec. 304. The Director of the Federal Emergency Management Agency is hereby authorized and directed to encourage the exploration, development, and mining of critical and strategic minerals and metals, and to make provision for the development of substitutes for strategic and critical materials, as authorized by and subject to the provisions of section 303 of the Defense Production Act of 1950, as amended.

[Sec. 304 amended by EO 10662 of Mar. 13, 1956, 21 FR 1673, 3 CFR, 1954-1958 Comp., p. 318; EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Sec. 305. The Director of the Federal Emergency Management Agency is hereby authorized and directed to make subsidy payments, to determine the amounts, manner, terms, and conditions thereof, and to make findings, as authorized by and subject to the provisions of section 303(c) of the Defense Production Act of 1950, as amended.

[Sec. 305 amended by EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Sec. 306. The functions conferred upon the President by section 303(e) of the Defense Production Act of 1950, as amended, with respect to the installation of additional equipment, facilities, processes, or improvements to plants, factories, and other industrial facilities owned by the United States Government, and with respect to the installation of Government-owned equipment in plants, factories, and other industrial facilities owned by private persons, are hereby delegated to the Administrator of General Services.

Sec. 307. The functions conferred upon the President by section 303(f) of the Defense Production Act of 1950, as amended, with respect to transfers to the stockpile referred to in the said section, are hereby delegated to the Director of the Federal Emergency Management Agency.

[Sec. 307 amended by EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Sec. 308. The authority conferred upon the President by section 304(b) of the Defense Production Act of 1950, as amended, to approve borrowing from the Treasury of the United States is hereby delegated to the Director of the Federal Emergency Management Agency.

[Sec. 308 amended by EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Sec. 309. All functions provided for in sections 303 to 307, inclusive, and in sections 310 and 311 of this order, shall be carried out within such amounts of funds as may be made available pursuant to the Defense Production Act of 1950, as amended.

Sec. 310. (a) The Secretary of the Treasury, hereafter in this section referred to as the Secretary, is hereby authorized and directed to make loans (including participations in, or guarantees of, loans) to private business enterprises (including research corporations not organized for profit) for the expansion of capacity, the development of technological processes, and the production of essential materials, including the exploration, development, and mining of strategic and critical metals and minerals, exclusive of such expansion, development and production in foreign countries, as authorized by and subject to section 302 of the Defense Production Act of 1950, as amended. The functions assigned to the Secretary by this section include the administration and servicing of all loans (including participations in, or guarantees of, loans) made by the Reconstruction Finance Corporation prior to September 29, 1953, pursuant to the said section 302.
(b) Loans under section 310(a) hereof (1) shall be made upon such terms and conditions as the Secretary shall determine, (2) shall be made only after the Secretary has determined in each instance that financial assistance is not available on reasonable terms from private sources or from other governmental sources, and (3) shall be made only upon certificate of essentiality of the loan, which certificate shall be made by the Director of the Federal Emergency Management Agency.
(c) Applications for loans under section 310(a) hereof shall be received from applicants by the Secretary or by such agencies of the Government as the Secretary shall designate for this purpose.

[Sec. 310 amended by EO 10489 of Sept. 26, 1953, 18 FR 6201, 3 CFR, 1949-1953 Comp., p. 972; EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Sec. 311. (a) The Export-Import Bank of Washington2 is hereby authorized and directed to make loans (including participations in, or guarantees of, loans) to private business enterprises, for the expansion of capacity, the development of technological processes, and the production of essential materials, including the exploration, development, and mining of strategic and critical metals and minerals, in those cases where such expansion, development or production is carried on in foreign countries, as authorized by and subject to section 302 of the Defense Production Act of 1950, as amended.
(b) Loans under section 311(a) hereof (1) shall be made upon such terms and conditions as the said Bank shall determine, (2) shall be made only after the Bank has determined in each instance that financial assistance is not available on reasonable terms from private sources and that the loan involved cannot be

made under the provisions of and from funds available to the Bank under the Export-Import Bank Act of 1945, as amended, and (3) shall be made only upon certificate of essentiality of the loan, which certificate shall be made by the Director of the Federal Emergency Management Agency.
(c) Applications for loans under section 311(a) hereof shall be received from applicants by the said Bank or by such agencies of the Government as the Bank shall designate for this purpose.

[Sec. 311 amended by EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Sec. 312. The functions conferred by sections 303, 305 and 306 of this order shall be carried out in accordance with programs certified by the Director of the Federal Emergency Management Agency. Each officer and agency of the Government having mobilization functions shall make recommendations to the Director of the Federal Emergency Management Agency for the issuance of certificates or other action under sections 302 and 303 of the Defense Production Act of 1950, as amended, and for the issuance of certificates under subsections (e) and (g) of section 168 of the Internal Revenue Code of 1954, with respect to the materials and facilities which are, pursuant to the designation of areas of production by the Director of the Federal Emergency Management Agency under section 301 of this order, as amended, within the jurisdiction of such officer or agency.

[Sec. 312 amended by EO 10574 of Nov. 5, 1954, 19 FR 7249, 3 CFR, 1954-1958 Comp., p. 212; EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Sec. 313. The Director of the Federal Emergency Management Agency is hereby authorized and directed to submit to the Congress the reports required by the second proviso of section 304(b) of the Defense Production Act of 1950, as amended.

[Sec. 313 amended by EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Part IV. Labor Supply

Sec. 401. The Secretary of Labor shall utilize the functions vested in him so as to meet most effectively the labor needs of defense industry and essential civilian employment, and to this end he shall:
(a) Assemble and analyze information on, and make a continuing appraisal of, the nation's labor requirements for defense and other activities and the supply of workers. All agencies of the Government shall cooperate with the Secretary in furnishing information necessary for this purpose.
(b) Consult with and advise each delegate of the Director of the Federal Emergency Management Agency referred to in section 201(a) of this order and each official of the Government exercising guarantee or loan functions under Part III of this order concerning (1) the effect of contemplated actions on labor supply and utilization, (2) the relation of labor supply to materials and facilities requirements, (3) such other matters as will assist in making the exercise of priority and allocations functions consistent with effective utilization and distribution of labor.
(c) Formulate plans, programs, and policies for meeting defense and essential civilian labor requirements.
(d) Utilize the public employment service system, and enlist the cooperation and assistance of management and labor to carry out these plans and programs and accomplish their objectives.
(e) Determine the occupations critical to meeting the labor requirements of defense and essential civilian activities and with the Secretary of Defense, the Director of Selective Service, and such other persons as the Director of the Federal Emergency Management Agency may designate develop policies applicable to the induction and deferment of personnel for the armed services, except for civilian personnel in the reserves.

[Sec. 401 amended by EO 11051 of Sept. 27, 1962, 27 FR 9683, 3 CFR, 1959-1963 Comp., p. 635; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Part V. Voluntary Agreements

Sec. 501. (a) The functions conferred upon the President by section 708(c)(1) and (d) of the Defense Production Act, as amended, are hereby delegated to the Director of the Federal Emergency Management Agency and, subject to the provisions of section 101 of this order, to the Secretary of Defense, the Secretary of the Interior, the Secretary of Agriculture, the Secretary of Commerce, and the Secretary of Transportation, except that for the purposes of carrying out the objectives of Title I of the Act, the authority granted in section 708(c)(1) of the Act shall be exercised only by the Director of the Federal Emergency Management Agency.
(b) The functions conferred upon the President by section 708(d) of the Defense Production Act and delegated under section 501(a) of this order, relating to the establishment of advisory committees, shall be exercised only after consultation with, and in accordance with guidelines and procedures established by, the Director of the Office of Management and Budget.

[Sec. 501 amended by EO 11956 of Jan. 13, 1977, 42 FR 2947, 3 CFR, 1977 Comp., p. 78; EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Part VI. General Provisions

Sec. 601. As used in this order:
(a) The term "functions" includes powers, duties, authority, responsibilities and discretion.
(b) The term "materials" includes raw materials, articles, commodities, products, supplies, components, technical information, and processes, but excludes fissionable materials as defined in the Atomic Energy Act of 1946.
(c) The term "petroleum" shall mean crude oil and synthetic liquid fuel, their products, and associated hydrocarbons, including pipelines for the movement thereof.
(d) The term "gas" shall mean natural gas and manufactured gas, including pipelines for the movement thereof.
(e) The term "solid fuels" shall mean all forms of anthracite, bituminous, subbituminous, and lignitic coals; coke; and coal chemicals.
(f) The term "electric power" shall mean all forms of electric power and energy, including the generation, transmission, distribution, and utilization thereof.
(g) The term "metals and minerals" shall mean all raw materials of mineral origin, including their refining and processing but excluding their fabrication.
(h) The term "food" shall mean all commodities and products, simple, mixed, or compound, or complements to such commodities or products, that are capable of being eaten or drunk by either human beings or animals, irrespective of other uses to which such commodities or products may be put, at all stages of processing from the raw commodity to the products thereof in vendible form for human or animal consumption. For the purposes of this order the term "food" shall also include all starches, sugars, vegetable and animal fats and oils, cotton, tobacco, wool, mohair, hemp, flax fiber, and naval stores, but shall not include any such material after it loses its identity as an agricultural commodity or agricultural product.

(i) The term "farm equipment" shall mean equipment manufactured for use on farms in connection with the production or processing of food.
(j) The term "fertilizer" shall mean fertilizer in form for distribution to the users thereof.
(k) The term "domestic transportation, storage, and port facilities" shall include locomotives, cars, motor vehicles, watercraft used on inland waterways, in harbors, and on the Great Lakes, and other vehicles, vessels, and all instrumentalities of shipment or carriage, irrespective of ownership, and all services in or in connection with the carriage of persons or property in intrastate, interstate, or foreign commerce within the United States, its Territories and possessions, and the District of Columbia, except movement of petroleum and gas by pipeline; and warehouses, piers, docks, wharves, loading and unloading equipment, and all other structures and facilities used in connection with the transshipment of persons and property between domestic carriers and carriers engaged in coastwise, intercoastal, and overseas transportation.

Sec. 602. (a) Except as otherwise provided in section 602(c) of this order, each officer or agency of the Government having functions under the Defense Production Act of 1950, as amended, delegated or assigned thereto by or pursuant to this Executive order may exercise and perform, with respect to such functions, the functions vested in the President by Title VII of the said Act.

(b) The functions which may be exercised and performed pursuant to the authority of section 602(a) of this order shall include, but not by way of limitation, (1) except as otherwise provided in section 708(c) of the Defense Production Act of 1950, as amended, the power to redelegate functions, and to authorize the successive redelegation of functions, to agencies, officers, and employees of the Government, (2) the power to create an agency or agencies, under the jurisdiction of the officer concerned, to administer functions delegated or assigned by or pursuant to this order, and (3) in respect of Part II of this order, the power of subpoena: Provided, That the subpoena power shall be utilized only after the scope and purpose of the investigation, inspection, or inquiry to which the subpoena relates have been defined either by the appropriate officer referred to in section 602(a) of this order or by such other person or persons as he shall designate.

(c) There are excluded from the functions delegated by section 602(a) of this order (1) the functions delegated by Part V of this Order, (2) the functions of the President with respect to regulations under section 710(b), (c), (d) and (e) of the Defense Production Act of 1950, as amended, and (3) the functions of the President with respect to fixing compensation under section 703(a) of the said Act.

(d)(1) The functions conferred upon the President by Section 309 of the Defense Production Act, as amended, with respect to the preparation and submission of reports to the Congress concerning offsets shall be performed by the Director of the Office of Management and Budget (OMB). The Director may further delegate to the heads of Executive departments and agencies responsibility for preparing and submitting for his review particular sections of such reports. The heads of Executive departments and agencies shall, to the extent provided by law, provide the Director with such information as may be necessary for the effective performance of these functions.

(2) In order to ensure that information gathered pursuant to this authority shall be subject to appropriate confidentiality protections, the Bureau of Economic Analysis of the United States Department of Commerce, which previously has been designated a "central collecting agency" in gathering this information under 44 U.S.C. 3509, is authorized pursuant to Section 705 of the Defense Production Act, as amended, to collect the information required for compilation of the data base to be used in preparation of the reports to Congress required by Section 309 of the Defense Production Act.

[Sec. 602 amended by EO 10662 of Mar. 13, 1956, 21 FR 1673, 3 CFR, 1954-1958 Comp., p. 318; EO 12521 of June 24, 1985, 50 FR 26335, 3 CFR, 1985 Comp., p. 374; EO 12649 of Aug. 11, 1988, 53 FR 30639, 3 CFR, 1988 Comp., p. 579]

Sec. 603. All agencies of the Government (including, as used in this order, departments, establishments, and corporations) shall furnish to each officer of the Government to whom functions under the Defense Production Act of 1950, as amended, are delegated or assigned by or pursuant to this order such information relating to defense production or procurement, or otherwise relating to the said functions, delegated or assigned to such officer by or pursuant to this order as may be required to perform those functions.

Sec. 604. The Defense Materials Procurement Agency established by Executive Order No. 10281 of August 28, 1951 (16 FR 8789), is hereby abolished and the personnel, records, property, and unexpended balances of appropriations, allocations and other funds thereof shall be transferred from it to the General Services Administration for use in connection with the functions assigned or delegated to the Administrator of General Services by or pursuant to this order or for purposes of liquidation, as the said Administrator shall determine.

Sec. 605. The Economic Stabilization Agency, established by Executive Order 10161 of September 9, 1950, is continued to October 31, 1953, under the direction of the Director of the Office of Defense Mobilization who shall serve ex officio as the Economic Stabilization Administrator for the purpose of winding up and liquidating the affairs of said Agency.

Sec. 606. All orders, regulations, rulings, certificates, directives and other actions relating to any function affected by this order shall remain in effect except as they are inconsistent herewith or are hereafter amended or revoked under proper authority, and nothing in this order shall affect the validity or force of anything heretofore done under previous delegations or other assignment of authority under the Defense Production Act of 1950 as amended.

Sec. 607. The following are superseded or revoked:
(1) Executive Order No. 10161 of September 9, 1950 (15 FR 6105).
(2) Executive Order No. 10169 of October 11, 1950 (15 FR 6901).
(3) Executive Order No. 10193 of December 16, 1950 (15 FR 9031).
(4) Executive Order No. 10200 of January 3, 1951 (16 FR 61).
(5) Executive Order No. 10223 of March 10, 1951 (16 FR 2247).
(6) Executive Order No. 10281 of August 28, 1951 (16 FR 8789).
(7) Executive Order No. 10324 of February 6, 1952 (17 FR 1171).
(8) Executive Order No. 10359 of June 9, 1952 (17 FR 5269).
(9) Executive Order No. 10373 of July 14, 1952 (17 FR 6425).
(10 Executive Order No. 10377 of July 25, 1952 (17 FR 6891).
(11 Executive Order No. 10390 of August 30, 1952 (17 FR 7995).
(12 Executive Order No. 10433 of February 4, 1953 (18 FR 761).
(13 Executive Order No. 10467 of June 30, 1953 (18 FR 3777).

Sec. 608. To the extent that any provision of any prior Executive Order (including Executive Order No. 10461 of June 17, 1953 (18 FR 3513)) is inconsistent with the provisions of this order, the latter shall control and such prior provision is amended accordingly. The following designated orders, modified as required to conform them to the provisions of this order, shall remain in effect:
Executive Order No. 10182 of November 21, 1950 (15 FR 8013), as amended by
Executive Order No. 10205 of January 16, 1951 (16 FR 419).
Executive Order No. 10219 of February 28, 1951 (16 FR 1983).
Executive Order No. 10224 of March 15, 1951 (16 FR 2543).

Sec. 609. Effective October 1, 1977, the Secretary of Energy shall exercise all authority and discharge all responsibility herein delegated to or conferred upon (a) the Atomic Energy Commission, and (b) with respect to petroleum, gas, solid fuels and electric power, upon the Secretary of the Interior.

[Sec. 609 added by EO 12038 of Feb. 3, 1978, 43 FR 4957, 3 CFR, 1978 Comp., p. 136]

Sec. 610. Whenever the Director, Federal Emergency Management Agency, believes that the functions of an Executive agency have been modified pursuant to law in such manner as to require the amendment of any Executive order which relates to the assignment of emergency preparedness functions or the administration of mobilization programs, he shall promptly submit any proposals for the amendment of such Executive orders to the Director of the Office of Management and Budget in accordance with the provisions of Executive Order No. 11030, as amended.

[Sec. 610 added by EO 12038 of Feb. 3, 1978, 43 FR 4957, 3 CFR, 1978 Comp., p. 136; amended by EO 12148 of July 20, 1979, 44 FR 43239, 3 CFR, 1979 Comp., p. 412]

Editorial note: The name of the Office of Emergency Planning was changed to the Office of Emergency Preparedness by Pub. L. 90-608 (82 Stat. 1194). The Office of Emergency Preparedness was abolished by Reorganization Plan No. 1 of 1973, 38 FR 9579, 3 CFR, 1971-1975 Comp., p. 1157, effective July 1, 1973, and certain functions were transferred to the Administrator of General Services by EO 11725 of June 27, 1973, 38 FR 17175, 3 CFR, 1971-1975 Comp., p. 779, which was revoked by Executive Order 12148 of July 20, 1979, Chapter 44.

1 Editorial note: The Atomic Energy Commission was abolished and its functions transferred to the Energy Research and Development Administration and the Nuclear Regulatory Commission by the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233). The functions of the Energy Research and Development Administration were transferred to the Department of Energy by the Department of Energy Organization Act (91 Stat. 565, 42 U.S.C. 7151), effective October 1, 1977.

2 Editorial note: Redesignated as the Export-Import Bank of the United States by Pub. L. 90-267 (82 Stat. 47, 12 U.S.C. 635 nt.).

Department of Agriculture Office of the Secretary Washington, D.C., 20250

June 19, 1995

Ms. Debby Moore President, Kansas environmentalists for Commerce in Hemp 2742 E. 2nd Wichita, Kansas, 67214

Dear Ms. Moore:

Thank you for your letter of April 10, 1995, regarding hemp Cannabis Sativa L.) and your publication Cannabis Sativa L. Hemp. As you well know, however, Cannabis Sativa L. is a Schedule I controlled substance (21 U.S.C. 812 (c) (10); 21 CFR 1308.11 (d) (17) and Federal law requires persons who manufacture it must obtain an annual registration from the Attorney General (12 U.S.C. 822). This registration is issued in accordance with Federal regulations found in 21 CFR Part 1301. For additional information, you should contact the Registration Unit, Drug Enforcement Administration, Department of Justice, P. O. Box 28083. Central Station, Washington, D.C., 20005. For information about the legal aspects of hemp production, we suggest you contact the Office of National Drug Control Policy, Executive Office of the President, Washington, D.C., 20500. The Department of Agriculture (USDA) has no jurisdiction over these statutes and regulations.

We acknowledge receipt of you business plan written in regard to Executive Order No., 12919, National Defense Industrial Resources Preparedness. Executive Order No. 12919, dated June 3, 1994, addresses national defense industrial resource policies and delegates to certain Cabinet members authorities conferred upon the President by the Defense Production Act of 1950, as amended, 50 U.S.C. App. 2061-2170 (the Act). Chief among these authorities is the President's power to require that capable contractors accept and give preference in the performance of those contracts which the President deems necessary or appropriate to promote the national defense. As you are aware, Section 201 (a) (1) of the Executive Order delegates to the Secretary of Agriculture (the Secretary) this authority of the President with respect to contracts for food resources, food resource facilities, and domestic distribution of farm equipment and commercial fertilizer. At Section 901 (e), the Executive Order defines "food resources" as commodities or products that are capable of being ingested by either human beings or animals and includes hemp, among other crops.

The Executive Order, however, does not require the Secretary to enter into contracts for the production of food resources. As shown above, the President enjoys discretion under the Act to determine which contracts are necessary or appropriate to promote the national defense. The Executive Order delegates this discretion to the Secretary with respect to food resources, but USDA has a policy not to require the acceptance and performance of contracts for the production of hemp.

As you are already aware, USDA discontinued research on hemp decades ago. It may be true that varieties presently grown for hallucinating purposes are short in stature as compared to those grown for the purposes. With modern day breeding methods, however, the hallucinating characteristics could easily be incorporated into the tall growing plants and they would be indistinguishable from each other.

We appreciate your contacting us on this issue

Sincerely,

Dan Glickman Secretary

Subj: RE:h yard/hempseed oil
Date: 09/09/1999 2:09:01 PM Eastern Daylight Time
From: oco2@cfsan.fda.gov (Lyn Goossens)
Reply-to: oco2@cfsan.fda.gov
To: henryyard@aol.com

Henry Yard:

Hempseed oil is an eatable oil, its draw back is that it is not
stable and can only be kept a week or two and it becomes rancid.
It is not a "drug" substance.
The Food and Drug Administration (FDA) does not have any
information on dietary supplement products for specific conditions
or safety of their use and has not pre-cleared their purported
claims; under DSHEA, the responsibility for determining the
appropriateness of a dietary supplement is the consumer, not FDA.
The Dietary Supplement Health and Education Act of 1994 exempts
dietary supplements from premarket review and approval and the
firms are not required to to submit safety or efficacy data to FDA.
The National Institutes of Health (NIH) Office of Alternative
Medicine may have some information on these products.
web sites: http://www.nih.gov/
http://altmed.od.nih.gov/

Lyn Goossens, MPH, RD
Office of Consumer Education, FDA, CFSAN
Email: oco2@cfsan.fda.gov
CFSAN Homepage: http://www.cfsan.fda.gov/
Hot Line: 1-800-332-4010 M-F Noon til 4pm

> Personal Information
> Name: Henry Yard
>
>
> (b6)
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> Question:
> I have been given a bottle of hempseed oil from a friend. He has
> informed me
> that it is safe for use as a salad oil and as a dietary
> supplement. Has this
> product been approved by the FDA for use as a food or as a food additive?
> Please let me know. Thank you, Henry Yard